6-2012

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Recommended Citation
Riegel, B. (2012). The Impact on Anxiety and Perceived Control of a Short One-on-One Nursing Intervention Designed to Decrease Treatment Seeking Delay in People With Coronary Heart Disease. *European Journal of Cardiovascular Nursing, 11* (2), 160-167.
http://dx.doi.org/10.1016/j.ejcnurse.2010.11.003

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Abstract

Background: Patient delay in seeking treatment for acute coronary syndrome symptoms remains a problem. Thus, it is vital to test interventions to improve this behavior, but at the same time it is essential that interventions not increase anxiety.Purpose: To determine the impact on anxiety and perceived control of an individual face-to-face education and counseling intervention designed to decrease patient delay in seeking treatment for acute coronary syndrome symptoms. Methods: This was a multicenter randomized controlled trial of the intervention in which anxiety data were collected at baseline, 3-months and 12-months. A total of 3522 patients with confirmed coronary artery disease were enrolled; data from 2597 patients with anxiety data at all time points are included. The intervention was a 45 min education and counseling session, in which the social, cognitive and emotional responses to acute coronary syndrome symptoms were discussed as were barriers to early treatment seeking. Repeated measures analysis of covariance was used to compare anxiety and perceived control levels across time between the groups controlling for age, gender, ethnicity, education level, and comorbidities. Results: There were significant differences in anxiety by group ($p = 0.03$). Anxiety level was stable in patients in the control group, but decreased across time in the intervention group. Perceived control increased across time in the intervention group and remained unchanged in the control group ($p = 0.01$).Conclusion: Interventions in which cardiac patients directly confront the possibility of an acute cardiac event do not cause anxiety if they provide patients with appropriate strategies for managing symptoms.

Keywords

pre-hospital delay, anxiety

Disciplines

Medicine and Health Sciences | Nursing

Published in final edited form as:
Eur J Cardiovasc Nurs. 2012 June ; 11(2): 160–167. doi:10.1016/j.ejcnurse.2010.11.003.

The impact on anxiety and perceived control of a short one-on-one nursing intervention designed to decrease treatment seeking delay in people with coronary heart disease

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Abstract

Background—Patient delay in seeking treatment for acute coronary syndrome symptoms remains a problem. Thus, it is vital to test interventions to improve this behavior, but at the same time it is essential that interventions not increase anxiety.

Purpose—To determine the impact on anxiety and perceived control of an individual face-to-face education and counseling intervention designed to decrease patient delay in seeking treatment for acute coronary syndrome symptoms.

Methods—This was a multicenter randomized controlled trial of the intervention in which anxiety data were collected at baseline, 3-months and 12-months. A total of 3522 patients with confirmed coronary artery disease were enrolled; data from 2597 patients with anxiety data at all

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time points are included. The intervention was a 45 minute education and counseling session, in which the social, cognitive and emotional responses to acute coronary syndrome symptoms were discussed as were barriers to early treatment seeking. Repeated measures analysis of covariance was used to compare anxiety and perceived control levels across time between the groups controlling for age, gender, ethnicity, education level, and comorbidities.

Results—There were significant differences in anxiety by group ($p = 0.03$). Anxiety level was stable in patients in the control group, but decreased across time in the intervention group. Perceived control increased across time in the intervention group and remained unchanged in the control group ($p = 0.01$).

Conclusion—Interventions in which cardiac patients directly confront the possibility of an acute cardiac event do not cause anxiety if they provide patients with appropriate strategies for managing symptoms.

The problem of prolonged prehospital delay in patients experiencing acute coronary syndrome symptoms has persisted over several decades [1,2]. The majority of patients, even those who have suffered a previous acute myocardial infarction, delay 2 hours or more from the onset of acute coronary syndrome symptoms before seeking treatment at a healthcare facility [3–5]. This delay time has been remarkably resistant to improvement despite multiple mass public education campaigns [6].

Innovative educational interventions targeted at reducing patient prehospital delay must continue to be tested because acute coronary syndrome outcomes are substantially improved the faster definitive treatment is given [2]. However, a potential deterrent to educating patients about the risk of ignoring acute coronary syndrome symptoms is the possibility that such interventions could increase patient anxiety and cause inappropriate cardiac-related vigilance and excess use of the emergency medical system. Anxiety in cardiac patients is associated independently with poor outcomes [7,8], and thus it is essential that educational interventions do not increase anxiety. Perceived control, the belief that one has at one's disposal strategies to reduce the aversiveness of an event, is associated with low levels of anxiety [7,9,10]. Educational strategies can increase sense of perceived control, thus reducing any anxiety associated with providing information about a future acute coronary syndrome event [11,12].

We tested an educational strategy designed to decrease cardiac patients' delay in seeking treatment for acute cardiac symptoms in a randomized controlled trial,[13] but found no differences in delay time between the control and intervention groups at the end of the study. [14] Given the potential of our intervention to increase patient anxiety, we conducted this secondary analysis in order to determine if anxiety did increase, thus possibly interfering the effectiveness of the intervention and explaining our no difference findings. Accordingly, the purpose of this study was to determine the impact on anxiety and perceived control of an individual face-to-face education and counseling intervention designed to decrease patient delay in seeking treatment for acute contrary syndrome symptoms.

METHODS

Design

Patients with known coronary heart disease were prospectively enrolled in this randomized controlled clinical trial from outpatient and inpatient cardiac units at community hospitals and academic medical centers in the United States, Australia and New Zealand. The design and methods have been described in detail previously [13–15]. Patients were randomized to either the intervention or a usual care control group. Randomization was done using

computer generated randomization in blocks. Data were collected at baseline (at enrollment and prior to delivery of the intervention), 3-months and 1-year.

Sample

Institutional review board approval was received from all participating sites and participants gave written informed consent prior to being randomized to one of the two study groups. Men and women of all ages with coronary heart disease were recruited to the study if they met the following inclusion criteria: 1) coronary heart disease diagnosis confirmed by patients' primary physician and/or medical records; and 2) living independently (i.e., not in an institutional setting). Patients were excluded if they had any of the following: 1) a complicating serious comorbidity such as renal failure; 2) untreated malignancy or neurological disorder with impaired cognition; 3) unable to read or understand English; and 4) uncorrected major hearing loss. A total of 3522 patients were enrolled; data from 2597 patients with complete anxiety data at all three time points are included here (Figure 1).

Intervention

The intervention was described in detail previously [13], but briefly, it was delivered by a trained cardiovascular nurse to individual patients and their significant others in a face-to-face session that typically lasted about 45 minutes. Using a flipchart with the main points listed and pictures illustrating main points, the information was delivered and counseling triggered. The intervention was standardized so that each patient received the same information, although it was individualized to his or her specific situation and questions. One month after the initial intervention session a research team nurse, usually the person who carried out the education and counseling intervention, called the patient to review main points. The nurse asked about cardiac symptoms in the intervening month and reinforced the need for fast action.

The intervention was designed to address the three areas recommended by National Heart Lung and Blood Institute Working Group on Educational Strategies to Prevent Prehospital Delay in Patients at High Risk for Acute Myocardial Infarction: 1) information; 2) emotional issues; and 3) social factors [16]. Study participants were given information about typical symptoms, possible variability in symptom presentation specific to their situation (e.g., older patients or those with diabetes), and were informed of the possibility that symptom onset may be gradual and intermittent, rather than stereotypical sudden crushing chest pain. Participants were also advised to take nitroglycerin tablets (if prescribed) and aspirin (if not contraindicated). In addition, patients were taught to call an ambulance immediately. Participants were provided with the National Heart Attack Alert Program advisory form for home use (available at www.nhlbi.nih.gov/health/public/heart/mi/core_bk.htm). This form includes the actions to take in response to heart attack symptoms and provides a space to write in the location of the nearest emergency department with appropriate cardiovascular services.

As part of the intervention, participants were counseled to anticipate the emotional responses to acute coronary syndrome symptoms. To accompany this aversive message, the benefits of seeking treatment promptly were emphasized. Participants were asked about prior experiences with the emergency department or healthcare, and about hospital admissions and were then asked to discuss negative experiences in seeking care. These experiences were reconciled with the current informational message and any ambiguities or uncertainties resolved. Emotional responses were addressed partially through the use of scenarios that most closely resemble the participants' circumstances. Participants were asked to rehearse their likely response to the onset of cardiac symptoms with the nurse to increase the likelihood of responding appropriately even when experiencing emotional reactions. By

providing participants with strategies for managing symptoms the intervention was intended to increase the sense of perceived control and thereby reduce anxiety.

Data Collection and Measurement

Data were collected using medical record review, patient interview, and written questionnaires at baseline, 3 months and 12 months. Instruments were administered in a place convenient and chosen by the patient (e.g., out-patient clinic, physician's office, or patient's home). Sociodemographic information (i.e., age, gender, education level, marital status, ethnicity, and health insurance status), clinical history (i.e., history of angina, myocardial infarction, revascularization (i.e., coronary artery bypass grafting and percutaneous coronary intervention), stroke, diabetes, and hypertension), and presence of risk factors (i.e., smoking, sedentary life style, body mass index) were collected from the medical record and patient interview. Data on anxiety and perceived control were obtained using self-report questionnaires.

Anxiety was measured using the Multiple Affect Adjective Checklist [17–19]. The Multiple Affect Adjective Checklist consists of 132 alphabetically arranged adjectives that represent the emotions of anxiety, depression and hostility. Respondents check all of the adjectives that describe how they have felt during the past week. Responses to relevant negative adjectives are summed and positive adjectives are subtracted to calculate scores for state anxiety (range 0–21). Higher scores indicate higher levels of the given emotion. A score of ≥ 11 is indicative of the presence of symptoms of anxiety [17–19]. This instrument has been used extensively in cardiac populations and has evidence of acceptable reliability and validity [17–19].

Perceived control was measured using the Control Attitudes Scale-Revised [20,21]. The instrument consists of 8 items that assess patients' perception of control related to their cardiac disease. Respondents rate their agreement with each item on a scale from 1 (strongly disagree) to 5 (strongly agree). Higher scores indicate higher levels of perceived control and a score of ≥ 32 indicates moderately high levels of perceived control, while a score of ≤ 16 suggests that patient has a low level of perceived control. The psychometrics of the instrument have been tested in a number of cardiac populations and it has demonstrated evidence of acceptable reliability and validity [21].

Data Analysis

Baseline sample characteristics were compared between the intervention and control groups using chi-square or *t*-tests as appropriate. Anxiety and perceived control were compared by sample characteristics using *t*-tests. Repeated measures analysis of covariance was used to examine patterns in the levels of anxiety across the three time periods between the intervention and control groups while controlling for age, gender, ethnicity, years of education, and comorbidities. The sphericity assumption was not met, therefore the Greenhouse-Geisser correction was applied.

RESULTS

Of the 2597 patients with anxiety data at all three data collection points, 1267 were randomized to the control group and 1330 to the intervention group. There were no differences in baseline characteristics between the groups with the exception that there were slightly more women in the intervention group (Table 1). Baseline levels of anxiety and perceived control also were similar between the groups (Table 1) and reflected a low level of anxiety and higher level of perceived control in the sample.

Participants differed in their levels of anxiety and perceived control based on a number of sociodemographic and clinical variables (Table 2). Women reported higher levels of anxiety and lower levels of perceived control; older patients reported lower levels of anxiety and higher levels of perceived control than younger participants; married or cohabitating patients reported lower levels of anxiety and higher levels of perceived control than the group of single, divorced or widowed people; and the least educated participants reported the highest levels of anxiety as did those with the lowest incomes, while perceived control did not differ based on education and income (Table 2). There were no differences in anxiety based on ethnicity, or past history of hypertension or myocardial infarction. Participants without hypertension, prior myocardial infarction and diabetes reported higher levels of perceived control.

Examination of the levels of anxiety across the three time periods revealed that there was a significant group by time interaction in the patterns of anxiety (Figure 2, $p = 0.03$). The groups were similar at baseline and 3 months, but diverged at 12 months with higher anxiety levels seen in the control group than the intervention groups ($p = 0.01$). These patterns remained consistent when controlling for age, ethnicity, education and comorbidities, but there was a group by gender by time interaction (Figure 3, $p = 0.01$). Anxiety levels were higher in women than in men at baseline and all time points. The decrease in anxiety in the intervention group across time after the intervention is attributable entirely to a decrease in anxiety in men. Among women, anxiety remained stable in the intervention group.

There was a significant group by time interaction in the patterns of perceived control across time with an increase in perceived control in the intervention group compared to the control group at both 3 and 12 month follow-up periods (Figure 4, $p = 0.01$). This pattern was consistent when controlling for age, gender, ethnicity, education, baseline anxiety level, and comorbidities. There was no gender interaction.

DISCUSSION

This study demonstrates that an intervention designed to decrease patient delay in seeking treatment for acute cardiac symptoms increases patients' sense of perceived control, and does not increase their anxiety levels. Compared to patients in the control group, participants in the intervention group experienced a decrease in anxiety after the intervention, although this decrease was seen only in men; however, in neither women nor men, did anxiety increase after the intervention. Perceived control, increased in both men and women at 3 and 12 months, while remaining unchanged in the control group.

Anxiety related to the heart or cardiac disease is a relatively common problem [22] and one with serious negative consequences [22]. Individuals with heart-focused anxiety have substantially greater health care utilization, and have higher rates of in-hospital complications and out-of-hospital morbidity and mortality [7,22–24]. Thus, it is imperative that healthcare providers avoid interventions that might increase anxiety. Given the complex relationship between information delivery, denial and anxiety in the context of a threatening situation [25,26], investigators and clinicians planning interventions designed to educate patients to respond appropriately to acute cardiac events must maintain a balance between providing enough information to reduce denial of the serious nature of acute coronary syndrome symptoms and potential lethal consequences of delaying treatment while not increasing anxiety excessively. These data demonstrate that even in an intervention focused on confronting symptoms of an acute, life-threatening cardiac event, anxiety is not increased and may be decreased when the intervention provides patients with the tools for managing symptoms. The slight increase in perceived control seen in the intervention group supports this contention. These data also demonstrate that an increase in anxiety in the intervention

group does not explain the negative findings from our intervention trial in which we saw no differences in delay time between the control and intervention groups.[14]

It is likely that our intervention was successful in abating increases in anxiety because it included two elements: 1) exercises designed specifically to increase participants' perception of control over their symptoms, and 2) discussion and defusing of emotional components of the individuals' responses to acute cardiac symptoms. In our individualized intervention, participants were able to discuss specific events that were distressing to them and to rehearse positive responses to a new event. Our intervention was based on the Leventhal self-regulatory model, in which cognitive and emotional responses operate on parallel, but partially independent levels, through phases of threat assessment, coping/ planning, and appraisal [27,28]. Our intervention may have prevented increases in anxiety because it strengthened the individual's belief in his/her ability to generate a positive action/ coping plan in response to a specific health threat (Leventhal's Phase 2). At the same time, it may have diminished negative, automatic emotional responses based on memories of past fear-based experiences across any of Leventhal's three phases.

Why this process may have been more effective in reducing anxiety in men than in women remains unclear. Recent findings in neurohormonal and aging research offer some insights. Neurohormonal studies in murine models suggest that anxiety levels in females may be related to estrogen levels; when estrogen is lowest, anxiety is higher in females than in males [29,30]. Further study is needed to fully explain the differential gender response to our intervention.

Extensive previous work from our group supports the current findings. We have previously demonstrated that anxiety can be attenuated in interventions that are potentially threatening when the intervention includes specific components that increase participants' sense of perceived control [11,12,31,32]. We have conducted a series of studies designed to determine the best ways to teach cardiopulmonary resuscitation to family members of high risk cardiac patients and high risk neonates while avoiding increasing participants' anxiety. Many clinicians avoided recommending cardiopulmonary resuscitation training for family members of high risk cardiac patients out of fear of increasing anxiety in both the family member and the patient. We have demonstrated that when cardiopulmonary resuscitation training is accompanied with a short, one-time support component that directly addresses participants' fears, that perceived control is increased and anxiety is decreased in both family members and patients [11,12,31,32].

Not only did anxiety not increase in the intervention group as a result of the intervention, there was a decrease in anxiety demonstrated for as long as one year after the intervention. This increase, however, was confined to men, while anxiety level was stable in women. The gender difference in the effect of the intervention may be related to the higher level of anxiety and the lower level of perceived control seen in women in this study. Similar to others, we demonstrated a substantially higher baseline level of anxiety in women compared to men, and lower levels of perceived control.[33,34]

In summary, this intervention, in which cardiac patients directly confronted the possibility of having a future acute cardiac event did not cause anxiety, likely because strategies for managing the event were part of the intervention as evidenced by the increase in perceived control seen. Clinicians should not be reluctant to counsel patients of appropriate actions to take when they experience acute cardiac symptoms out of fear of causing undue anxiety in their patients.

Acknowledgments

Funding acknowledgement: NIH R01 # R01 NR007952 from the National Institute of Nursing Research. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institute of Nursing Research or the National Institutes of Health.

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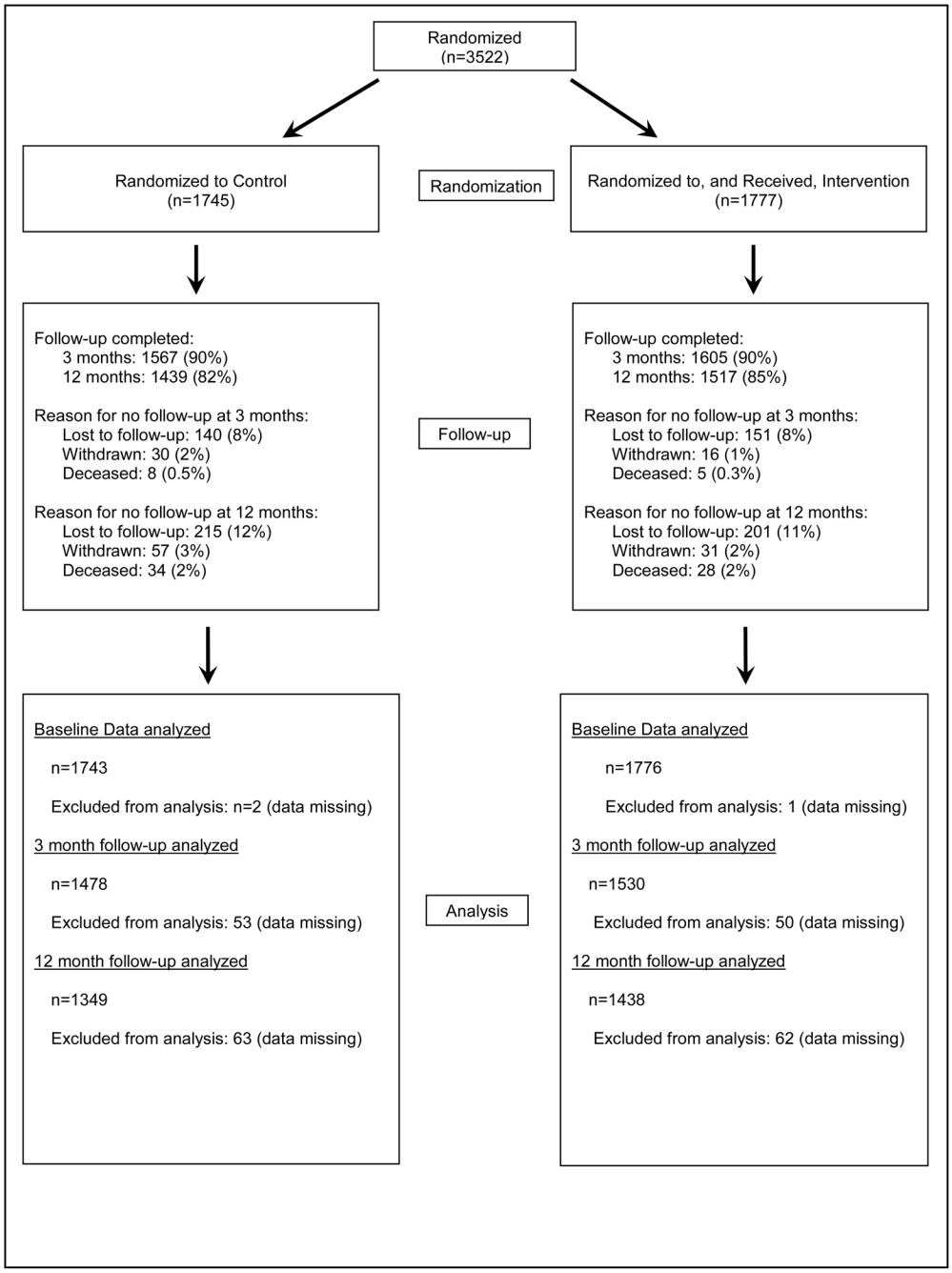


Figure 1.
Consort Diagram

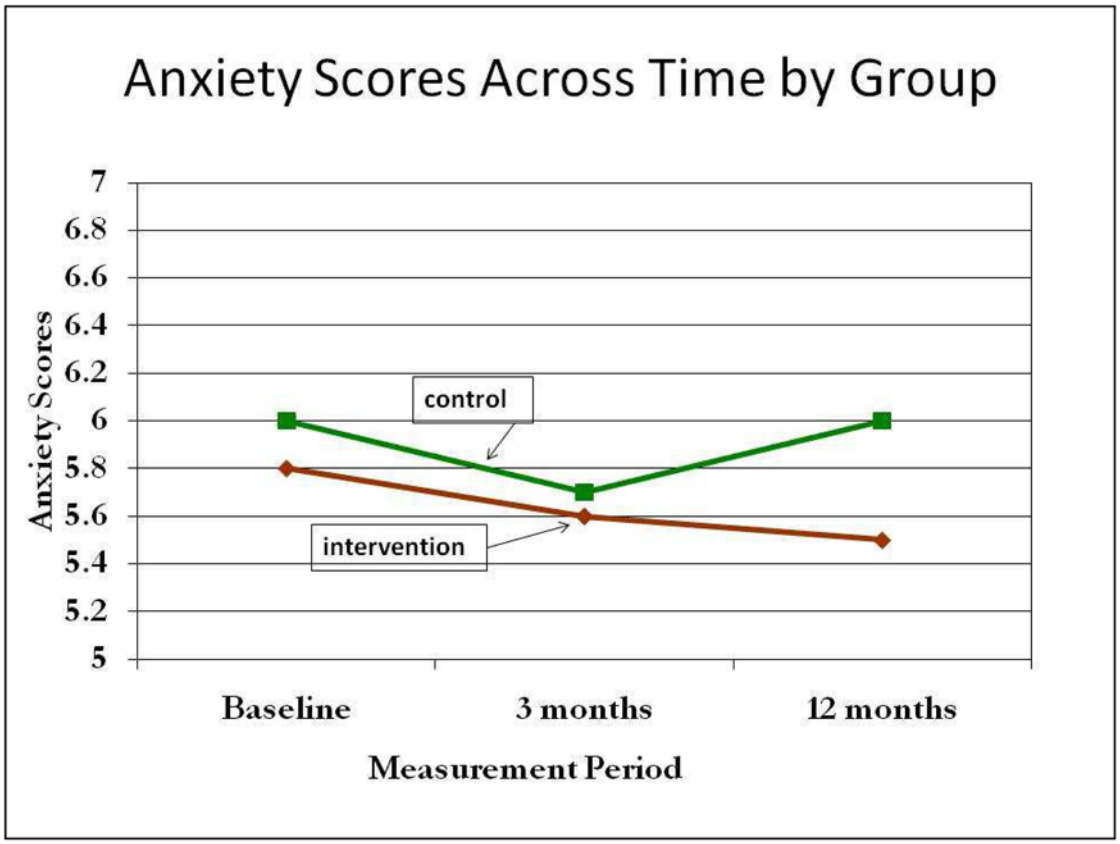
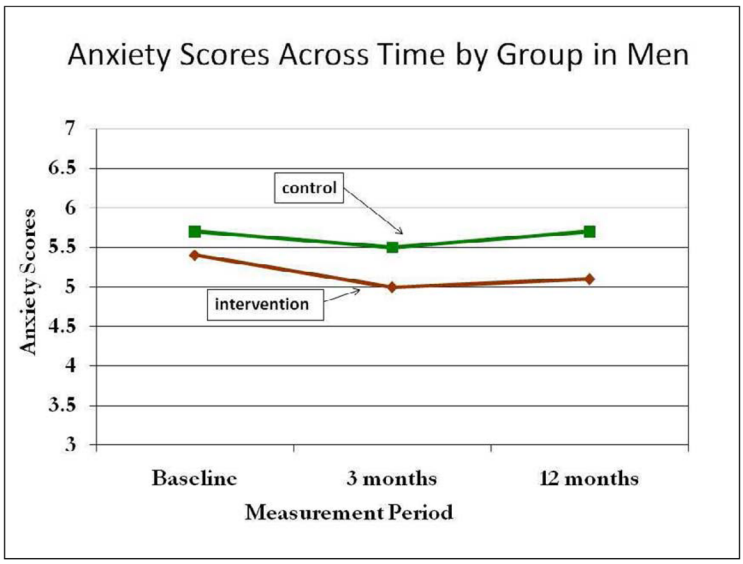

Anxiety Scores Across Time by Group
Anxiety Scores
7
6.8
6.6
6.4
6.2
6
5.8
5.6
5.4
5.2
5
control
intervention
Baseline
3 months
12 months
Measurement Period

Figure 2.


Anxiety Scores Across Time by Group in Men
Anxiety Scores
7
6.5
6
5.5
5
4.5
4
3.5
3
control
intervention
Baseline
3 months
12 months
Measurement Period

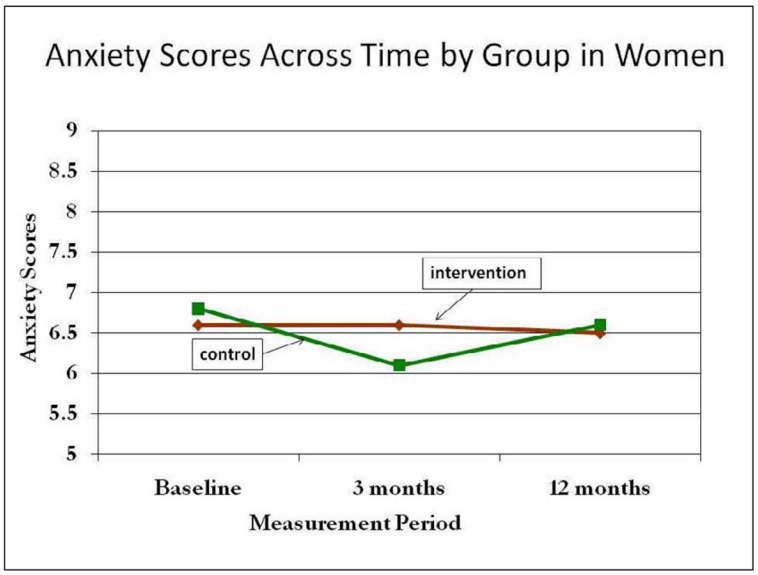

Anxiety Scores Across Time by Group in Women
Anxiety Scores
9
8.5
8
7.5
7
6.5
6
5.5
5
intervention
control
Baseline
3 months
12 months
Measurement Period

Figure 3.

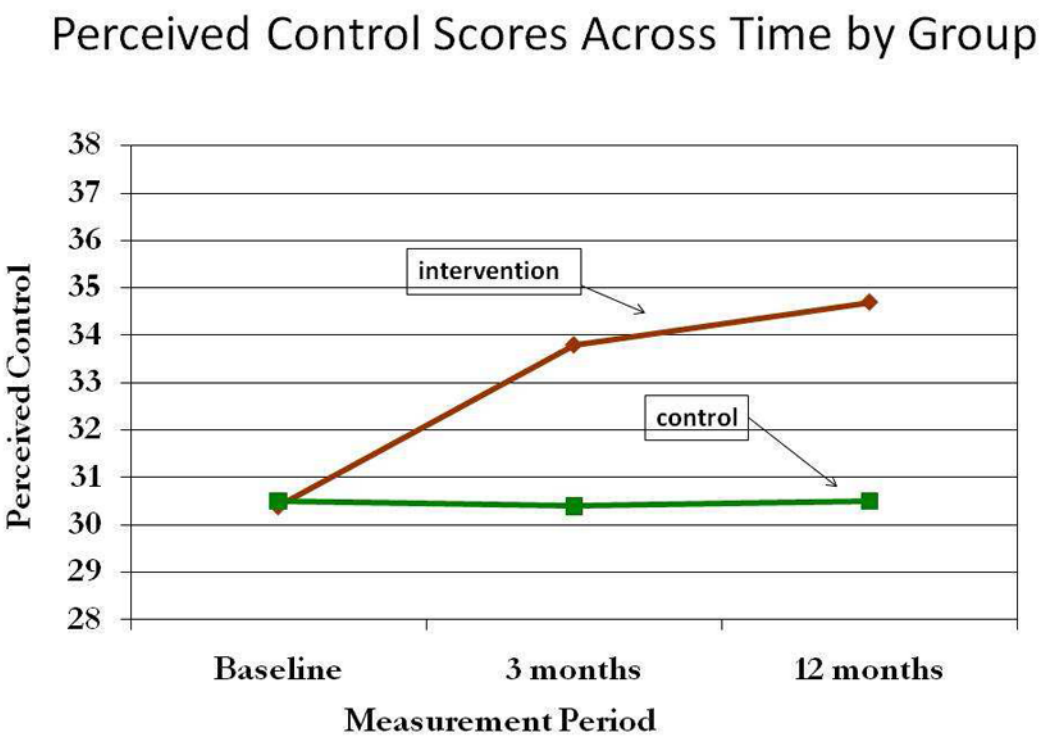

Perceived Control Scores Across Time by Group
38
37
36
35
34
33
32
31
30
29
28
Perceived Control
intervention
control
Baseline
3 months
12 months
Measurement Period

Figure 4.

Table 1

Baseline characteristics of study participants by group (N = 2597).

Characteristic	Control (n = 1267) Mean ±SD or N (%)	Intervention (n = 1330) Mean ±SD or N (%)	P *
Female gender	382 (30.1)	459 (34.5)	.019
Age, years	68 ± 10	68 ± 11	.46
Currently married	916 (72.4)	950 (71.5)	.63
Education			
-High school or less	600 (34.4)	598 (33.7)	.64
-Beyond high school	1142 (65.6)	1178 (66.3)	
Ethnicity			
-Caucasian	1173 (92.6)	1228 (92.3)	.73
Health insurance			
-Uninsured or government only	644 (51.0)	665 (50.2)	.72
-Any private insurance	619 (49.0)	659 (49.8)	
Clinical history			
-Angina	765 (62.1)	798 (61.9)	.90
-Myocardial infarction	683 (55.3)	696 (53.9)	.47
-Percutaneous coronary intervention	605 (48.2)	637 (48.7)	.84
-Coronary artery bypass grafts	605 (47.9)	600 (45.2)	.18
-Stroke	109 (8.7)	136 (10.4)	.16
-Diabetes	260 (20.7)	266 (20.1)	.77
-Hypertension	657 (52.4)	719 (54.8)	.24
Risk factors			
-Current smoker	63 (5.0)	60 (4.5)	.58
-Sedentary	388 (30.8)	419 (31.6)	.67
-Body mass index	27.3 ± 4.9	27.4 ± 5.0	.49
Psychosocial status			
-Anxiety level	6.0 ± 4.1	5.8 ± 4.0	.13
-Perceived control level	30.4 ± 4.0	30.4 ± 4.1	.81

* Fisher's exact Chi-square for categorical data and t-test for continuous data

Table 2

Comparison of levels of anxiety and perceived control based on sociodemographic and clinical history (N=2597).

Variable	Anxiety Mean ± SD	*P* value	Perceived Control Mean ± SD	*P* value
Gender				
Male	5.5 ± 3.9	< 0.001	30.7 ± 4.0	< 0.001
Female	6.7 ± 4.2		29.8 ± 4.2	
Age, years		< 0.001		0.010
≤ 65	6.5 ± 4.3		30.1 ± 4.4	
> 65	5.5 ± 3.9		30.6 ± 3.8	
Ethnicity		0.647		0.568
Caucasian	5.9 ± 4.1		30.4 ± 4.0	
Others	6.0 ± 4.0		30.3 ± 4.1	
Marital status		0.002		0.035
Married or cohabitate	5.7 ± 4.0		30.5 ± 4.0	
Single, divorced, or widowed	6.3 ± 4.0		30.2 ± 4.1	
Highest education achieved		< 0.001		0.797
< High school	6.7 ± 4.1[a]		30.5 ± 3.9	
High school	6.1 ± 4.0[b]		30.5 ± 3.8	
Some college	5.7 ± 4.0[b]		30.3 ± 4.1	
Baccalaureate or graduate school	5.4 ± 4.1[b]		30.5 ± 4.2	
Annual income		0.009		0.192
< $15,000	6.4 ± 4.0[a]		30.4 ± 4.0	
$15,000 – $29,999	6.0 ± 4.0		30.3 ± 4.1	
$30,000 – $ 44,999	5.8 ± 4.0[b]		30.5 ± 3.8	
$45,000 – $ 59,999	5.5 ± 4.0[b]		30.4 ± 4.1	
≥ $60,000	5.6 ± 4.0[b]		30.8 ± 4.1	
Comorbidities				
Hypertension		0.275		0.001
Yes	5.8 ± 4.0		30.2 ± 4.0	
No	6.0 ± 4.1		30.7 ± 4.1	
Prior MI		0.923		0.028
Yes	5.9 ± 4.1		30.3 ± 4.1	
No	5.9 ± 4.0		30.6 ± 3.9	
Diabetes		< 0.001		< 0.001
Yes	6.4 ± 4.1		29.8 ± 4.2	
No	5.7 ± 4.0		30.6 ± 4.0	

Notes. MI = Myocardial infarction; Groups with different superscripts are significantly different from each other